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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,615	02/08/2001	Kaname Nakahara	216208US0XPCT	8496

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EXAMINER
SHEIKH, HUMERA N

ART UNIT	PAPER NUMBER
1615	18

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/762,615	Applicant(s) NAKAHARA ET AL.	
	Examiner Humera N. Sheikh	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-9,19,20 and 32-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-9,19,20 and 32-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Application

Receipt of the Amendment filed 06/04/03 is acknowledged.

The 35 U.S.C. 102(b) rejection has been withdrawn.

Claims 1, 4-9, 19, 20 and 32-38 are pending. Claims 1 and 36 have been amended. New claim 38 has been added. Claims 1, 4-9, 19, 20 and 32-38 stand rejected.

Claim Rejections - 35 USC § 103

Claims 1, 4-9, 19, 20 and 32-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pfister *et al.* (US Pat. No.5, 232,702) in view of Mantelle (US Pat. No.5,446,070) and further in view of Wick *et al.* (US Pat. No. 5,662,926).

Pfister et al. teach a silicone pressure-sensitive adhesive transdermal drug delivery patch comprising a minimum of five layers which comprise a support body, a liquid reservoir layer for storing medicaments, a rate controlling membrane, pressure sensitive adhesive and a release liner wherein the transdermal patch includes various drugs, such as cardiovascular agents and anti-anginal agents (see reference column 8, lines 28-68); (column 9, lines 1-23) and Figs. 3 and 4.

Pfister teaches that the transdermal delivery device, as seen in Fig. 3, includes a minimum of five layers, wherein the first layer is a backing substrate, the second layer includes a liquid reservoir which may contain bioactive agents, drugs, excipients, enhancers, co-solvents or mixtures thereof. The reservoir-type transdermal device may include drugs selected from cardiovascular agents, anti-anginal agents, anti-arrythmic agents, etc and mixtures thereof. Also included are enhancers, excipients selected from the group consisting of polyols, surfactants, fatty acid esters, etc. The third layer is a rate controlling membrane, which acts as the rate controlling mechanism for the delivery of the liquid drug(s), co-solvents, enhancers and excipients from the reservoir. The fourth layer is a pressure sensitive adhesive and the fifth layer is a silicone pressure sensitive adhesive release liner (col. 8, lines 35-62).

Pfister does not explicitly teach the properties of water-vapor permeability of 100-g/m square or more at 40^0 C and 24 hours for the adhesive. However, it would have been deemed obvious to one of ordinary skill in the art at the time the invention was made that suitable vapor permeability ranges could be determined through routine or manipulative experimentation and in addition, since the materials used by Pfister et al. are the same, they would also provide for similar properties and results as the claimed invention.

Pfister, is deficient also in the sense that he does not explicitly teach nicorandil in the formulation.

Mantelle teaches compositions and methods for the administration of pharmaceutically active agents, wherein the composition is in the form of a bioadhesive suitable for a variety of drugs, such as anti-anginal agents, cardiotonic drugs, such as dopamine and vasodilators, such as nicorandil (see reference column 4, lines 25-44); (col. 12, lines 10-15); (col. 41, lines 9-20).

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Mantelle within the teachings of Pfister because Mantelle teaches a bioadhesive composition with the incorporation of various drugs, which include anti-anginal agents, cardiotonic drugs, such as dopamine and vasodilators, such as nicorandil in the formulation and Pfister explicitly teaches the use of cardiovascular and anti-anginal agents in his transdermal preparation. The expected result would be an improved and highly effective bioadhesive preparation for the treatment of various disorders.

Pfister et al. and Mantelle are lacking in the sense that they do not teach a layer of adhesive which comprises an acrylic adhesive and/or a rubber type adhesive.

Wick teaches a transdermal patch having a polymer film incorporated with an active agent wherein the transdermal patch comprises a pressure-sensitive adhesive material selected from silicon adhesives, acrylic adhesives and synthetic rubber adhesives (see reference col.16, line 64 thru col. 17, line 32); and (claim 12).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the combined teachings of Wick within Pfister and Mantelle because Wick, who teaches various adhesive materials, also teaches that acrylic, rubber and silicone-based adhesives can be suitably used and similarly, Pfister teaches a silicone pressure-sensitive adhesive transdermal drug delivery patch and Mantelle teaches a bioadhesive composition for the delivery of active agents. The expected result would be a transdermal delivery system for the effective delivery of active agents.

Response to Arguments

Applicant's arguments filed 06/04/03 have been fully considered but they are not persuasive.

Firstly, the applicant argued regarding the 35 U.S.C. 102(b) rejection that, "Pfister does not teach a medicine storage layer comprising one or more medicines that permeate, dissolve, disperse or diffuse into a plasticized permeation control film which has been activated by moisture. Moreover, it does not anticipate the claims because it does not disclose and acrylic or a rubber-based adhesive as now required by claim 1."

This argument has been fully considered and was found to be persuasive in view of the applicant's amendment. Hence, the 35 U.S.C. 102(b) rejection has been withdrawn.

Secondly, the applicant argued regarding the 35 U.S.C. 103(a) rejections over Pfister et al. ('702) in view of Mantelle ('070) stating, "neither Pfister nor Mantelle disclose the acrylic or rubber-type adhesives as now required by independent claim 1. Secondly, neither Pfister nor Mantelle disclose or suggest the combination of a solid medicine storage layer and a permeation controlling film, which is a water-soluble polymer that is plasticized when activated by moisture and permits the permeation of medicine in the medicine storage layer."

These arguments have been fully considered, but were not found to be persuasive. Pfister teaches a silicone pressure-sensitive adhesive transdermal drug delivery patch comprising five layers of a support body, reservoir for storing medicaments, a rate controlling membrane, adhesive and a release liner wherein drugs, such as cardiovascular agents and anti-anginal agents can be included. Fig. 3 of Pfister demonstrates a reservoir-type transdermal delivery device, which comprises a minimum of five layers from top to bottom. The transdermal device can include drugs, enhancers, excipients, such as polyols, surfactants and the like. The second layer includes a liquid reservoir, which contains the drugs, bioactive agents, etc. This reservoir is similar in means and effect of the medicine storage layer and serves an identical purpose as that of the medicine storage layer. The third layer, which is the rate controlling membrane layer acts as the rate controlling mechanism for the delivery of the drugs, excipients, etc from the reservoir and hence is similar in means and effects as the instant permeation controlling film since the bioactive agent passes from the reservoir through the rate controlling membrane. The applicant's attempt to distinguish over the prior art therefore

is not seen as persuasive since the transdermal mechanism and device of Pfister achieves the same desired purpose as the applicant. The applicant's argument that a liquid rather than a solid medicine storage layer is taught is not persuasive since one of ordinary skill would be able to modify the various forms (i.e., liquid, solid) of medicine storage layers based on the intended purpose. Furthermore, the applicant's argument that Pfister or Mantelle do not disclose or suggest an acrylic or rubber-type adhesive as now required by independent claim 1 is not persuasive since the newly cited reference of Wick, explicitly teaches a transdermal patch comprises a pressure-sensitive adhesive material selected from silicon adhesives, acrylic adhesives and synthetic rubber adhesives (see reference col.16, line 64 thru col. 17, line 32); and (claim 12). The reference of Wick was relied upon to show the equivalency between acrylic, rubber and silicones as adhesives. No invention or patentability is seen in the substitution of one for the other. The prior art recognizes the ingredients as being equivalent.

Lastly, the applicant argued, "Mantelle refers to a large variety of drug compounds including nicorandil and various adhesives, but does not remedy the deficiencies of Pfister. That is, this document does not suggest a device having a solid medicine storage layer in combination with water soluble polymer permeation controlling film, nor does it suggest that a medicine, such as nicorandil, would permeate, dissolve, disperse or diffuse into a plasticized permeation controlling film which has been activated by moisture."

These arguments have been fully considered, but were not found to be persuasive. The argument that Mantelle does not suggest a medicine (nicorandil) which would permeate, dissolve, disperse or diffuse into a plasticized permeation controlling film which has been activated by moisture is disagreed upon since this is in actuality, a future intended use. The examiner points out that a future intended use without structural limitation holds no patentable weight. Furthermore, Mantelle was relied upon for the sole teaching of the obviousness of incorporating the combination of various drugs, such as – dopamine and particularly vasodilators, such as nicorandil in transdermal applications. As such, Mantelle resolves this deficiency of Pfister. The applicant's argument that a liquid rather than a solid medicine storage layer is taught is not persuasive since one of ordinary skill would be able to modify the various forms (i.e., liquid, solid) of medicine storage layers based on the intended purpose. The prior art teaches the effective transdermal delivery of drugs using a similarly formulated bioadhesive composition. The argument that a water soluble polymer permeation controlling film is not taught was also not found to be persuasive since Pfister teaches an equally equivalent rate controlling membrane which serves to control the rate of delivery of drugs and excipients. Furthermore, the use of water soluble polymers (i.e., polyvinyl alcohol) is included in the transdermal preparation of Pfister. Hence, the instant invention remains obvious and unpatentable over the prior art.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns

August 04, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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